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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BABIC, CHRISTOPHER M	

ART UNIT	PAPER NUMBER
1637	

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12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,458	GHARIZADEH, BABACK	
	Examiner	Art Unit	
	Christopher M. Babic	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☒ Claim(s) *2-12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claim(s) 1-12 are pending. The following Office Action is in response to Applicant's response dated October 9, 2007.

New Grounds Claim Objections

Claim(s) 2-12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 1 recites three specific types of sequencing reactions, whereas dependent claim(s) 2-12 encompasses sequencing reactions different to those recited in claim 1, effectively broadening the coverage of independent claim.

Withdrawn Claim Rejections - 35 USC § 112 - Indefiniteness

The rejection of claim(s) 12, as set forth in the previous Office Action dated July 11, 2007, has been withdrawn in view of Applicant's amendment.

New Grounds Claim Rejections - 35 USC § 112 - Indefiniteness

The following new grounds of rejection is made in view of Applicant's amendment to claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 2-12 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the sequencing reaction" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim(s) 2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tully et al. (WO 96/06187; 29 February 1996).

With regard to claim(s) 2, Tully teaches methods of multiplex sequencing utilizing sequencing primers comprising a mobility identifier (abstract; pg. 5 and 6, for example). Specifically, Tully teaches methods comprising the steps of: (a)

providing a sample containing nucleic acid molecules (middle pg. 2, Tully teaches samples with one or more types; middle pg. 10, Tully teaches their methods as useful for screening for microorganisms, for example); (b) providing a mixed pool of at least two **structurally different** sequencing oligonucleotide primers, whereby each primer is designed for being specific for one type or species or group or target chosen from the known set of types or target of the nucleic acid sample, thereby allowing a primer, which is specific for a type, species, group or target that is present in the sample, to hybridize in or close to the target or variable region (middle-end pg. 5, Tully teaches the use of multiple sequencing primers comprising a mobility identifier, for example); (c) mixing the sample and mixed pool of specific primers under conditions allowing a primer or primers to hybridize if a target type or types are present in the sample (middle pg. 2, Tully teaches multiplex sequencing, for example); (d) determining the type, species or target region to which the primer or primers have hybridized by extending the hybridized primer or primers in a DNA sequencing reaction (middle pg. 5, Tully teaches determining different sequencing with PAGE, for example).

With regard to claim(s) 2, Tully teaches sequencing utilizing multiple labeled ddNTPs (middle pg. 3, for example).

With regard to claim(s) 3, Tully teaches their methods as useful for screening for microorganisms (middle pg. 10, for example).

With regard to claim(s) 4 and 5, Tully teaches samples with one or more types (middle pg. 2, for example).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Given the indefiniteness of the claim language (see section USC 112(2)) and the fact that claim 2 effectively broadens the claimed method such that it encompasses the sequencing methods according to Tully, the rejection is maintained.

2. Claim(s) 2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ye et al. ("Fluorescent microsphere-based readout technology for multiplexed human single nucleotide polymorphism analysis and bacterial identification" Hum Mutat. 2001 Apr;17(4):305-16).

With regard to claim(s) 2, Ye teaches methods of multiplex sequencing utilizing sequencing primers comprising a unique zipcode sequences (abstract; fig. 1, for example). Specifically, Ye teaches methods comprising the steps of: (a) providing a sample containing nucleic acid molecules (pg. 307, col. 2, Ye teaches amplification of 16S rDNA from multiple bacterial species, for example); (b) providing a mixed pool of at least two **structurally different** sequencing oligonucleotide primers, whereby each primer is designed for being specific for one type or species or group or target chosen from the known set of types or target of the nucleic acid sample, thereby allowing a primer, which is specific for a type, species, group or target that is present in the sample, to hybridize in or

close to the target or variable region (pg. 308, col. 1, Ye teaches ASPE reactions as outlined in fig. 1, for example); (c) mixing the sample and mixed pool of specific primers under conditions allowing a primer or primers to hybridize if a target type or types are present in the sample (pg. 308, col. 1, Ye teaches ASPE reactions as outlined in fig. 1, for example); (d) determining the type, species or target region to which the primer or primers have hybridized by extending the hybridized primer or primers in a DNA sequencing reaction (pg. 309, col. 1, Ye teaches flow cytometric analysis, for example).

With regard to claim(s) 2, Ye teaches ASPE reactions as outlined in fig. 1 (pg. 308, col. 1, for example).

With regard to claim(s) 3-5, Ye teaches amplification of 16S rDNA from multiple bacterial species, for example (pg. 307, col. 2, for example).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Given the indefiniteness of the claim language (see section USC 112(2)) and the fact that claim 2 effectively broadens the claimed method such that it encompasses the sequencing methods according to Ye, the rejection is maintained.

New Grounds of Claim Rejections - 35 USC § 102

The following new grounds of rejections are made in view of Applicant's amendment to claim 1.

The text of those sections of Title 35, U.S. Code not included in this rejection can be found above.

Claim(s) 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bray et al. ("High-throughput multiplex SNP genotyping with MALDI-TOF mass spectrometry: practice, problems and promise" Hum Mutat. 2001 Apr;17(4):296-304).

Bray teaches methods of multiple DNA sequencing utilizing mass spectrometry sequencing (abstract; materials and methods, multiplex PCR and mini-sequencing reactions, for example). Specifically, Bray teaches methods comprising the steps of: (a) providing a sample containing nucleic acid molecules (pg. 297, DNA sample prep. and PCR, Bray teaches multiplex PCR; fig. 1, for example); (b) providing a mixed pool of at least two **structurally different** sequencing oligonucleotide primers, whereby each primer is designed for being specific for one type or species or group or target chosen from the known set of types or target of the nucleic acid sample, thereby allowing a primer, which is specific for a type, species, group or target that is present in the sample, to hybridize in or close to the target or variable region (pg. 298, mini-sequencing reactions; table 2; fig. 2,3, for example); (c) mixing the sample and mixed pool of specific primers under conditions allowing a primer or primers to hybridize if a target type or types are present in the sample (pg. 298, mini-sequencing reactions; table 2; fig. 2,3, for example); (d) determining the type, species or

target region to which the primer or primers have hybridized by extending the hybridized primer or primers using mass spectrometry DNA sequencing) (pg. 298, mini-sequencing reactions; table 2; fig. 2,3, for example).

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claim(s) 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tully et al. (WO 96/06187; 29 February 1996) in view of Rady et al. ("Type-specific primer-mediated direct sequencing of consensus primer-generated PCR amplicons of human papillomaviruses: a new approach for the simultaneous detection of multiple viral type infections. J Virol Methods. 1995 Jun;53(2-3):245-54").

The methods of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach sequencing of HPV.

With regard to claim(s) 6-10, Rady provides a supporting disclosure that teaches the amplification of a conserved region within multiple different HPV

types and subsequent sequencing with sequence specific primers (page 246-249, materials and methods; fig. 1, for example).

With regard to claim(s) 11, the sequencing of low yield amplification of fragments is inherent to the methods of Tully.

With regard to claim(s) 12, the primers according to Tully are designed to anneal to unspecific amplification products.

Thus, in summary, it is submitted that it would have been *prima facie obvious* to a skilled artisan at the time of invention to utilize the methods according to Tully to detect certain HPV types within a sample since Tully demonstrates such methods as capable of identifying many different nucleic acid templates within the same reaction, thereby reducing the time needed for many separate reactions.

Response to Arguments

Applicant's arguments have been addressed with respect to the previously applied reference(s).

2. Claim(s) 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ye et al. ("Fluorescent microsphere-based readout technology for multiplexed human single nucleotide polymorphism analysis and bacterial identification" Hum Mutat. 2001 Apr;17(4):305-16) in view of Rady et al. ("Type-specific primer-mediated direct sequencing of consensus primer-generated PCR amplicons of human papillomaviruses: a

new approach for the simultaneous detection of multiple viral type infections. J Virol Methods. 1995 Jun;53(2-3):245-54").

The methods of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach sequencing of HPV.

With regard to claim(s) 6-10, Rady provides a supporting disclosure that teaches the amplification of a conserved region within multiple different HPV types and subsequent sequencing with sequence specific primers (page 246-249, materials and methods; fig. 1, for example).

With regard to claim(s) 11, the sequencing of low yield amplification of fragments is inherent to the methods of Ye.

With regard to claim(s) 12, due to the indefiniteness of the claim (see above 112, 2nd section), the teachings of Ye appear to anticipate the intended limitations of the instant claims. The primers of Ye are designed to anneal to unspecific amplification products.

Thus, in summary, it is submitted that it would have been *prima facie obvious* to a skilled artisan at the time of invention to utilize the methods according to Ye to detect certain HPV types within a sample since Ye demonstrates such methods as capable of identifying many different nucleic acid templates within the same reaction, thereby reducing the time needed for many separate reactions.

Response to Arguments

Applicant's arguments have been addressed with respect to the previously applied reference(s).

Conclusion

Claim(s) 1-12 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone

number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/5/07

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